REMARKS

Claims 1, 2, 4-11, and 25-54 were rejected and remain pending. Claim 1 has been amended herein to indicate that the immunogenic polypeptide lacks a CH1 domain of IgE. The specification as filed fully supports this amendment. For example, the working examples as well as Figure 2 disclose multiple polypeptides lacking a CH1 domain of IgE. Thus, no new matter was added. In light of this amendment and the following remarks, Applicant respectfully requests reconsideration and allowance of claims 1, 2, 4-11, and 25-54.

Rejections under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 1-2, 4-11, and 25-54 under 35 U.S.C. §112, first paragraph, for the reasons set forth in the Official Actions mailed July 3, 2000 and January 2, 2001. Specifically, the Examiner stated that the claims do not recite a specific piece of the CH3 domain. The Examiner concluded that claims reciting merely a portion of CH3 are not enabled because the portion is not defined and could include as little as a single amino acid of CH3, which would be insufficient to generate the claimed anti-self response.

Applicant respectfully disagrees. Present claims 1, 25, and 48 indicate that the immunogenic polypeptide must contain at least a portion of a CH3 domain of IgE and must induce an anti-self IgE response. In addition, present claim 33 indicates that the self IgE portion must consist essentially of an N-terminal portion of a CH3 domain of IgE, and present claim 41 indicates that the non-self IgE portion must comprise an IgE sequence present in a non-placental mammal. A person of ordinary skill in the art reading Applicant's specification would have been able to make and use such immunogenic polypeptides to induce an anti-self IgE response. For example, a person of ordinary skill in the art would have understood from Figure 2 and Example 1 of Applicant's specification that polypeptides containing CH3 truncations induce an anti-self IgE response. In addition, a person of ordinary skill in the art would have been able to follow the teachings set forth in Examples 2 and 4-7 of Applicant's specification to produce, purify, and test polypeptides containing portions of CH3.

Thus, taken together, Applicant's specification fully enables the presently claimed invention. In light of the above, Applicant respectfully requests withdrawal of the rejection of claims 1-2, 4-11, and 25-54 under 35 U.S.C. §112, first paragraph.

The Examiner rejected claims 1-2, 4-11, and 25-54 under 35 U.S.C. §112, first paragraph, stating that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. Specifically, the Examiner asserted that the specification and the claims as originally filed do not provide support for the invention as now claimed owing to the following phrases: consists essentially of (claims 1 and 33); lacks a CH1 domain of IgE (claim 25); lacks light chain Ig sequences (claim 48). The Examiner further asserted that Figure 2 does not provide support for generic, or subgeneric, claims encompassing the newly cited limitations.

Applicant respectfully disagrees. The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language (see In re Edwards, 558, 568 F.2d 1349, 196 USPQ 465 (CCPA 1978); In re Herschler, 591 F.2d 693, 200 USPQ 711 (CCPA 1979)). The content of the drawings may also be considered in determining compliance with the written description requirement (see In re Barker, 559 F. 2d 588, 194 USPQ 470 (CCPA 1977)). In addition, ipsis verbis disclosure is not necessary to satisfy the written description requirement of section 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question (see Fujikawa v. Wattanasin, 93 F.3d 1559, 39 USPQ2d 1895 (Fed. Cir. 1996)).

Applicant's specification as filed provides adequate written description for the presently claimed invention. For example, a person of ordinary skill in the art reading Applicant's specification would have understood from Figure 2 that the inventor was in possession of multiple polypeptides that (1) contain non-self IgE portions consisting essentially of a CH2 domain of IgE and a CH4 domain of IgE, (2) lack a CH1 domain of IgE, (3) contain a self IgE portion consisting essentially of an N-terminal portion of a CH3 domain of IgE, or (4) lack light

chain Ig sequences. In addition, a person of ordinary skill in the art reading Applicant's specification would have understood from Examples 2, 4-8, and 10 that the inventor was in possession of methods for expressing, purifying, and detecting polypeptides within the scope of the presently claimed invention, as well as their use to induce an immune response, to determine antibody cross reactivity, and to develop vaccine conjugates with or without cytokine activity. Thus, taken together, it would have been clear to a person of ordinary skill in the art that Applicant's specification reasonably conveys that the Applicant was in possession of the subject matter presently claimed. In light of the above, Applicant respectfully requests withdrawal of the rejection of claims 1-2, 4-11, and 25-54 under 35 U.S.C. §112, first paragraph.

Rejection under 35 U.S.C. §102(b)

The Examiner rejected claims 1, 4-7, and 10-11 as being anticipated by Nissim *et al.* (In: Methods: A Companion to Methods in Enzymology, 8:124-132 (1995)). The Examiner stated that Nissim *et al.* teaches an immunogenic polypeptide comprising self and non-self domains of IgE. Specifically, the Examiner characterized Nissim et al. as teaching "a peptide of the composition humanCH2-mouseCH3-humanCH4," concluding that Nissim *et al.* anticipates the claimed invention.

Applicant respectfully disagrees. To further prosecution, however, claim 1 has been amended to recite an immunogenic polypeptide that lacks a CH1 domain of IgE. At no point does the Nissim *et al.* reference disclose an immunogenic polypeptide that lacks a CH1 domain of IgE. In fact, each composition disclosed in the Nissim *et al.* reference is a chimeric polypeptide containing CH1, CH2, CH3, and CH4 domains. Thus, the Nissim *et al.* reference does not anticipate the presently claimed invention. In light of the above, Applicant respectfully requests withdrawal of the rejection of claims 1, 4-7, and 10-11 under 35 U.S.C. §102(b).

CONCLUSION

Attached is a marked-up version of the changes being made by the current amendment. Applicant submits that claims 1, 2, 4-11, and 25-54 are in condition for allowance, which action is requested. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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Version with markings to show changes made

In the claims

Claim 1 has been amended as follows:

1. (Amended Thrice) An immunogenic polypeptide, comprising a self IgE portion and a non-self IgE portion, wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal, wherein said self IgE portion comprises at least a portion of a CH3 domain of IgE, [and] wherein said non-self IgE portion consists essentially of a CH2 domain of IgE and a CH4 domain of IgE, and wherein said immunogenic polypeptide lacks a CH1 domain of IgE.